

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: BENNEKER ET AL.
Title: CRYSTALLINE PAROXETINE METHANE
SULFONATE
Patent No.: 7,598,271
Issue Date: 10/06/2009
Examiner: Celia Chang
Art Unit: 1625
Confirmation Number: 9739

**SUPPLEMENTAL RENEWED REQUEST FOR RECONSIDERATION OF PTA
UNDER 37 C.F.R. §1.705 & RESPONSE TO DECISION ON PETITION**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Supplemental to the Renewed Request for Reconsideration of PTA and Response to Decision on Petition filed by the Applicants on October 22, 2009, Applicants note that the PTO is now following the Federal Circuit decision in *Wyeth v. Kappos*, that affirmed the district court decision.

In particular, in *Wyeth v. Kappos*, No. 2009-1120 (Jan. 7, 2010), the Federal Circuit determined that "[b]efore the three-year mark, no 'overlap' can transpire between the A delay and the B delay," and that "[i]f an A delay occurs on one day and a B delay occurs on a different day, those two days do *not* 'overlap' under section 154 (b)(2)" (emphasis added).

Applicants respectfully await a decision on their renewed request for reconsideration of PTA (filed October 22, 2009) that was responsive to the communication mailed August 26, 2009, that dismissed Applicants' Request for Reconsideration of Patent Term Adjustment for the captioned patent filed May 21, 2009. Applicants again *renew* that portion of their Request that was dismissed as premature and *request reconsideration* of that portion of their Request that was dismissed on the merits. Applicants hereby reiterate their reasoning on both issues as follows:

PTA Due To PTO Failure to Issue Patent Within Three Years (§ 1.702(b) Delay)

The August 26, 2009, communication notes that Applicants' Request for Reconsideration of PTA relates in part to the PTO's failure to issue the patent within 3 years of the filing date, and states that the Office's computers will not undertake the 37 CFR § 1.702(b) calculation until the actual date of issuance has been determined, even when an RCE has been filed that stops the accrual of additional PTA under § 1.702(b). Thus, the communication finds Applicants' request for reconsideration on this ground "premature," and states that such requests should be filed after the patent grants, within two months of the grant date, under § 1.705(d).

The patent at issue granted October 6, 2009; thus, the renewed Request for Reconsideration was timely filed within two months of the grant date on October 22, 2009.

Applicants believe that the PTA determination for the patent was made in accordance with the "Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. §154(b)(2)(A)" published at 69 Fed. Reg. 34238 (Jun. 21, 2004). Under that interpretation of the PTA statute, any PTO delay under 35 U.S.C. § 154(b)(1)(A) is deemed to overlap with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B), and so, as a practical effect, PTA may be awarded under §154(b)(1)(A) or §154(b)(1)(B), but not both.

As noted above, the PTO is now following the Federal Circuit has issued a decision in *Wyeth v. Kappos*, that affirmed the district court decision. In particular, in *Wyeth v. Kappos*, No. 2009-1120 (Jan. 7, 2010), the Federal Circuit determined that "[b]efore the three-year mark, no 'overlap' can transpire between the A delay and the B delay," and that "[i]f an A delay occurs on one day and a B delay occurs on a different day, those two days do *not* 'overlap' under section 154 (b)(2)" (emphasis added). Thus, the PTA for the captioned patent must be recalculated.

PTA Due To PTO Delay During Prosecution (§ 1.702(a) Delay)

Applicants' Request for Reconsideration of PTA filed on October 22, 2009, also relates to the PTO's failure to award PTA based on PTO delay during prosecution, namely, the PTO's failure to issue an Office Action under 35 U.S.C. § 132 or a Notice of Allowance under 35 § U.S.C. 151 within four months of the Reply filed by Applicants on May 31, 2001 (a Response to Restriction Requirement), which delay is awarded under 37 CFR § 1.702(a). That delay starts September 30, 2001 (four months after the Reply) and extends through September 19, 2008, when the PTO issued a Notice of Allowance, which was the first notice issued by the PTO that "stops the clock" under § 1.702(a) after Applicants' May 31, 2001 Reply.

The Office alleges that the Notice of Suspension mailed August 2, 2001¹ is a "notification under 35 U.S.C. § 132" that "stops the clock for determining examination delay" under § 1.703(a)(2), which allegedly did not start running again until the favorable decision by the Board of Patent Appeals and Interferences issued on May 25, 2004.

¹ The Notice of Suspension is incorrectly classified as a "Letter Suspending Prosecution At Applicant's Request." As set forth in the "Request for Clarification of Suspension Letter" filed August 28, 2001, Applicants did not request suspension of prosecution. Applicants had previously raised the possibility of an interference in a paper filed January 31, 2001, and the PTO suspended prosecution "[d]ue to a potential interference" on February 21, 2001. However, the Office Action mailed April 21, 2001 reopened prosecution. Applicants replied to that Action on the merits, and did not thereafter request suspension of prosecution or declaration of an interference. Thus, the suspension was PTO-initiated, not applicant-initiated.

The Office cites no authority for its position that the Notice of Suspension is an action “under 35 U.S.C. § 132.” Indeed, the Office’s position that the Notice of Suspension constitutes a notification under 35 U.C.S. § 132 that “stops the clock” under § 1.703(a)(2) is contrary to the plain language of 37 C.F.R. § 1.703(a)(2) and 35 U.S.C. §132.

According to 37 C.F.R. § 1.703(a)(2):

“The period of adjustment under §1.702(a) is the sum of the following periods . . . (2) The number of days, if any in the period beginning on the day after the date that is four months after the date a reply under §1.111 was filed and ending on the date of mailing of either ***an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151***, whichever occurs first....

An action under § 132 must include a rejection, objection or requirement to which an applicant must reply in order to continue prosecution:

Whenever, on examination, any claim for a patent is **rejected, or any objection or requirement made**, the Director shall notify the applicant thereof, stating the reasons for such **rejection, or objection or requirement**, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, **the application shall be reexamined....**

35 U.S.C. § 132(a) (emphasis added).

The Notice of Suspension did not include any “rejection or objection or requirement.” To the contrary, it stated that the pending claims “are allowable,” but that “due to a potential interference, *ex parte* prosecution is suspended.” Moreover, the Notice of Suspension did not require any reply from Applicants, or set any time period for reply. Thus, it does not have any of the hallmarks of a notice under 35 U.S.C. § 132.

That the Notice of Suspension should not “stop the clock” of PTO delay under § 1.703(a)(2) is further underscored by the fact that Applicants could have done nothing to

advance prosecution at that point. Indeed, prosecution had been suspended. A suspension of prosecution cannot constitute an action under § 132 merely because the PTO initiated the suspension. To the contrary, a suspension of action is a delay caused by the PTO, and the Notice of Suspension serves only as an express admission of the PTO's delay. No provision of the Patent Term Adjustment rules allows the PTO to overlook such delay.

Treating the Notice of Suspension as an action that "stops the clock" under § 1.703(a)(2) also is inconsistent with MPEP § 709(II), which states that "[s]uspension of action at the initiative of the Office should be avoided, if possible, because such suspension will cause delays in examination . . . and may lead to . . . patent term extension, or adjustment, due to the suspension." Thus, the MPEP expressly contemplates that PTO-initiated suspensions, such as that at issue here, constitute PTO delay that should be counted towards PTA.

III. Summary and Calculation of PTA

In view of the foregoing, Applicants have recalculated PTA for the captioned patent under the *Wyeth* court's interpretation of 37 CFR §1.703(b) and without treating the Notice of Suspension as an action under 35 U.S.C. § 132, and have determined that the patent is entitled to a total of 2514 days PTA, as shown on the attached sheet, which shows the relevant delays under 37 CFR §§1.702(a), (b) and (c), 37 CFR §§1.703(a), (b) and (c), and 37 CFR § 1.704(c). Applicants therefore respectfully request that the application be accorded **2514 days PTA**.

Specifically, 2,546 days of PTA should be accorded under 37 CFR § 1.702(a) and 37 CFR §1.703(a)(2) due to the Office delay beginning on September 30, 2001, which was four months after the Applicants filed a response to the Restriction Requirement, and ending on the day the Notice of Allowance was issued on September 19, 2008. Additionally, 33 days of PTA should be accorded under 37 CFR § 1.702(a) and 37 CFR §1.703(a)(6) due to the PTO's failure to issue the patent within four months of the issue fee payment made October 1, 2008, until Applicants filed a Request for Deferral of Issuance on March 6, 2009. Further, 15 days of PTA should be accorded under 37 CFR § 1.702(a) and 37 CFR §1.703(a)(6) due to the PTO's failure

to issue the patent within four months of the issue fee payment made May 21, 2009, until the patent issued in October 6, 2009.

Additionally, 135 days of PTA should be accorded under 37 CFR § 1.702(b) and 37 CFR §1.703(b)(2) due to the PTO's failure to issue the patent within three years, not including the time consumed by the interference, taking into account periods of overlapping delay under 37 CFR §1.702(a) (as interpreted by the *Wyeth* district court), and not including time consumed by the Request for Continued Examination filed March 6, 2009.²

The delay due to the interference (603 days) overlaps entirely with the 2,546 day period of delay requested under 37 CFR § 1.702(a) and 37 CFR §1.703(a)(2), and so is accounted for above. Should the Office determine that Applicants are not entitled to PTA for the full 2,546 day period, the Office must ensure that Applicants are credited for the full period of delay due to the interference, as required by 37 CFR § 1.702(c) and 37 CFR § 1.703(c)(1).

Finally, Applicants note that, under 37 CFR §1.704(c)(2), 215 days of Applicant delay may need to be deducted from the total PTA due to Applicants' request for Deferral of Issuance filed March 6, 2009, although it is not clear that that provision applies when accrual of PTO delay under 37 CFR §1.703(b)(2) has been tolled by the filing of an RCE on the same date.

Thus, Applicants request that the application be accorded **2514 days PTA**.

The patent is not subject to a terminal disclaimer. A terminal disclaimer was filed in the application; however, a petition to withdraw the Terminal Disclaimer was granted on April 16, 2008.

² Applicants' original Request for Reconsideration stated that 168 days delay was due under 37 CFR §1.703(b)(2); however, having reviewed the PTA rules, Applicants believe that 33 days of PTA previously requested under 37 CFR §1.703(b)(2) should be accorded under 37 CFR

Applicants believe no additional fee is due for this supplemental petition and request for reconsideration. However, the Commissioner is authorized to charge any fees which may be due, or credit any overpayment, to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 2, 2010

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§1.703(a)(6) due to the PTO's failure to issue the patent within four months of the issue fee payment made October 1, 2008, before the Request for Deferral of Issuance filed March 6, 2009.

Patent Term Adjustment Calculation System

Add a new event to this case

Docket Number: 091856-0111

Application Number: 09/200743

Patent Number: N/A

	Event Description	Event Date	Days from Filing	PTO Days	Applicant Days
Edit Delete	Application Filing Date	11/27/2000	0		
Edit Delete	Restriction Requirement	04/26/2001	150		
Edit Delete	Restriction Requirement Response Received at PTO	05/31/2001	185		
	Restriction Requirement Response Filed + 4 months	09/30/2001	307		
Edit Delete	IDS NOT falling under 1.704(c)(6), (8) or (10) filed at PTO	03/20/2002	478		
Edit Delete	Interference Declared	10/01/2002	673		
	3 Year Period Starts	11/27/2003	1,095		
Edit Delete	Interference Decided	05/25/2004	1,275	(603)	
Edit Delete	Notice of Allowance	09/19/2008	2,853	(2546)	
Edit Delete	Issue Fee Paid	10/01/2008	2,865		
	Issue Fee Paid + 4 months	02/01/2009	2,988		
Edit Delete	Request for Deferral of Issuance received at PTO	03/06/2009	3,021	(33),(33)	
Edit Delete	Request For Continued Examination (including amendment)	03/06/2009	3,021	(1926) 2714	
	3 Year Period Stopped	03/06/2009	3,021		
Edit Delete	Notice of Allowance	04/17/2009	3,063		
Edit Delete	Issue Fee Paid	05/21/2009	3,097		
	Issue Fee Paid + 4 months	09/21/2009	3,220		
Edit Delete	Patent Grant Date	10/06/2009	3,235	(15),(15) 15	215
Totals:				2,729	215
PTA:				2,514	